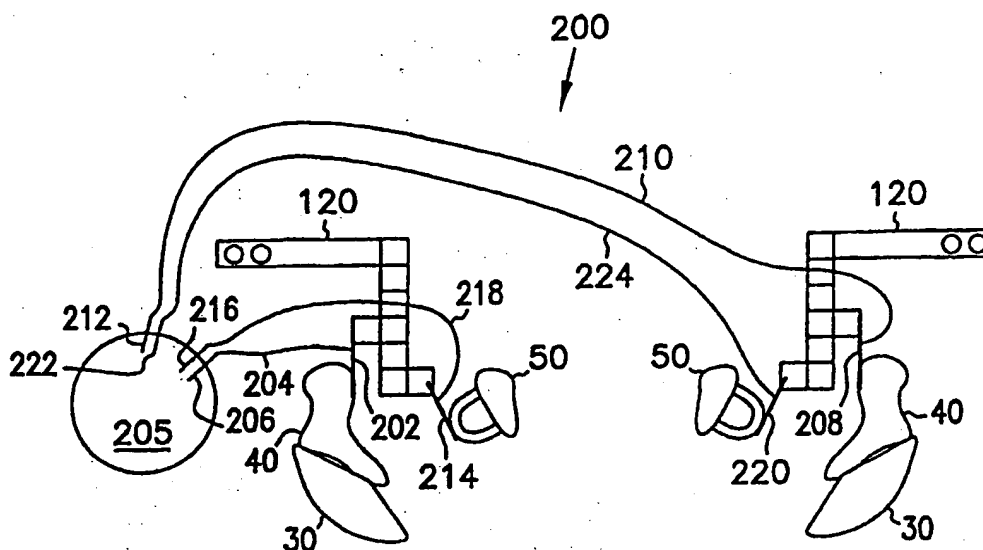




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : H04R	A2	(11) International Publication Number: WO 98/26629 (43) International Publication Date: 18 June 1998 (18.06.98)
(21) International Application Number: PCT/US97/21431 (22) International Filing Date: 24 November 1997 (24.11.97) (30) Priority Data: 08/755,180 25 November 1996 (25.11.96) US (71) Applicant: ST. CROIX MEDICAL, INC. [US/US]; Suite 418, 5155 East River Road, Minneapolis, MN 55421 (US). (72) Inventors: KROLL, Kai; 5217 West Mill Road, Minnetonka, MN 55345 (US). KENNEDY, Joel, A.; 1716 Chatham Avenue, Arden Hills, MN 55112 (US). (74) Agents: KEOUGH, Steven, J. et al.; Patterson & Keough, P.A., 1200 Rand Tower, 527 Marquette Avenue South, Minneapolis, MN 55402 (US).		(81) Designated States: JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>Without international search report and to be republished upon receipt of that report.</i>

(54) Title: DUAL PATH IMPLANTABLE HEARING ASSISTANCE DEVICE**(57) Abstract**

A dual path implantable hearing assistance system transduces sound vibrations of the malleus in one or both ears into electrical signals, processes the electrical signals to provide one or more resulting output electrical signals, and transduces the output signals into mechanical vibrations provided to the stapes in one or both ears. Communication between an electronics device and at least one ear is either wireless or through subcutaneous lead wires. The system may have two input paths and two output paths, programmable to provide the function of two separate single path systems, but capable of combining the signals such as by weighted summing. The system may also have two input paths and one output path; or, one input path and two output paths; or, one input path and one output path, each associated with a different ear.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

Dual Path Implantable Hearing Assistance Device

The Field of the Invention

This invention relates to an electromechanical hearing assistance device for use in an at least partially implantable middle ear hearing
5 system.

Background

In some types of partial middle ear implantable (P-MEI) or total middle ear implantable (T-MEI) hearing aid systems, sounds produce
10 mechanical vibrations which are transduced by an electromechanical input transducer into electrical signals. These electrical signals are in turn provided to a device which amplifies the signal and provides it to an electromechanical output transducer. The electromechanical output transducer vibrates an ossicular bone in response to the applied amplified
15 electrical signals, thus improving hearing.

A typical single path electronic hearing assistance system for amplifying signals received from an input transducer has a single input path for receiving the signal, circuitry to produce the desired output electrical signal, and a single output path for providing the output signal
20 to an output transducer. Such devices are useful for assisting hearing in only one ear. If a person requires assistance in both ears, two devices must be used, one for each ear.

Summary

25 The invention provides an at least partially middle ear implantable dual path electronic hearing assist system and method of use in both of a person's ears. The invention includes components for implantation within the middle ear regions of each ear, and provides: dual input paths; or, dual output paths; or, both dual input paths and dual output paths; or,
30 a single input path corresponding to a first ear and a single output path corresponding to a second ear. The system is capable of use as a partial

- 2 -

middle ear implantable (P-MEI) hearing aid system or a total middle ear implantable (T-MEI) hearing aid system.

In one embodiment, the invention simulates two single path devices. Each middle ear has an implanted input transducer and an
5 implanted output transducer. Each input transducer transduces mechanical sound vibrations into electrical signals that are separately provided to a dual path device. The device processes the received electrical signals and provides a resulting output electrical signals to drive each output transducer and produce mechanical output vibrations, such as
10 to the stapes in each middle ear.

In another embodiment, each middle ear has an input transducer for transducing mechanical sound vibrations into electrical signals that are separately provided to the device. The device processes the received electrical signals and provides a single resulting electrical output signal to
15 one output transducer in one middle ear. The output transducer transduces the electrical output signal into mechanical output vibrations in the middle ear in which the output transducer is disposed.

In another embodiment, each middle ear has an output transducer for receiving output electrical signals from the device that are transduced
20 into mechanical output vibrations. Only a single input transducer is used, disposed within one of the middle ears for receiving mechanical sound vibrations that are transduced into an electrical signal provided to the device.

In another embodiment, a first middle ear has an input transducer
25 for transducing received mechanical sound vibrations into an electrical input signal provided to the device. The device processes the received electrical input signal and provides an output electrical signal to an output transducer disposed within a second middle ear. The output transducer in the second middle ear transduces the received electrical signal into
30 mechanical output vibrations in the second middle ear.

- 3 -

Thus, the invention uses only one electronic device for providing various types and combinations of hearing assistance in both ears of a hearing impaired person.

5

Brief Description of the Drawings

In the drawings, like numerals describe substantially similar components throughout the several views.

Figure 1 illustrates a frontal section of an anatomically normal human ear in which the invention operates.

10

Figure 2 is a schematic illustration of one embodiment of the invention for assisting hearing in both first and second ears using a dual path electronic device.

Figure 3 is a schematic illustration of another embodiment of the invention using wireless communication between the electronic device and the second ear.

Figure 4 is a schematic illustration of another embodiment of the invention including two input paths and one output path.

Figure 5 is a schematic illustration of another embodiment of the invention including one input path and two output paths.

20

Figure 6 is a schematic illustration of another embodiment of the invention including one input path corresponding to a first ear, and one output path corresponding to a second ear.

Detailed Description

25

The invention provides an electronic device which is particularly advantageous when used in a middle ear implantable hearing aid system such as a partial middle ear implantable (P-MEI), total middle ear implantable (T-MEI), or other hearing aid system. A P-MEI or T-MEI hearing aid system assists the human auditory system in converting acoustic energy contained within sound waves into electrochemical signals delivered to the brain and interpreted as sound. Figure 1 illustrates generally a human auditory system. Sound waves are directed into an

30

- 4 -

external auditory canal 20 by an outer ear (pinna) 25. The frequency characteristics of the sound waves are slightly modified by the resonant characteristics of the external auditory canal 20. These sound waves impinge upon the tympanic membrane (eardrum) 30, interposed at the terminus of the external auditory canal 20, between it and the tympanic cavity (middle ear) 35. Variations in the sound waves produce tympanic vibrations. The mechanical energy of the tympanic vibrations is communicated to the inner ear, comprising cochlea 60, vestibule 61, and semicircular canals 62, by a sequence of articulating bones located in the middle ear 35. This sequence of articulating bones is referred to generally as the ossicular chain 37. Thus, the tympanic membrane 30 and ossicular chain 37 transform acoustic energy in the external auditory canal 20 to mechanical energy at the cochlea 60.

The ossicular chain 37 includes three primary components: a malleus 40, an incus 45, and a stapes 50. The malleus 40 includes manubrium and head portions. The manubrium of the malleus 40 attaches to the tympanic membrane 30. The head of the malleus 40 articulates with one end of the incus 45. The incus 45 normally couples mechanical energy from the vibrating malleus 40 to the stapes 50. The stapes 50 includes a capitulum portion, comprising a head and a neck, connected to a footplate portion by means of a support crus comprising two crura. The stapes 50 is disposed in and against a membrane-covered opening on the cochlea 60. This membrane-covered opening between the cochlea 60 and middle ear 35 is referred to as the oval window 55. Oval window 55 is considered part of cochlea 60 in this patent application. The incus 45 articulates the capitulum of the stapes 50 to complete the mechanical transmission path.

Normally, prior to implantation of the invention, tympanic vibrations are mechanically conducted through the malleus 40, incus 45, and stapes 50, to the oval window 55. Vibrations at the oval window 55 are conducted into the fluid-filled cochlea 60. These mechanical vibrations generate fluidic motion, thereby transmitting hydraulic energy within the

- 5 -

cochlea 60. Pressures generated in the cochlea 60 by fluidic motion are accommodated by a second membrane-covered opening on the cochlea 60. This second membrane-covered opening between the cochlea 60 and middle ear 35 is referred to as the round window 65. Round window 65 is considered part of cochlea 60 in this patent application. Receptor cells in the cochlea 60 translate the fluidic motion into neural impulses which are transmitted to the brain and perceived as sound. However, various disorders of the tympanic membrane 30, ossicular chain 37, and/or cochlea 60 can disrupt or impair normal hearing.

Hearing loss due to damage in the cochlea is referred to as sensorineural hearing loss. Hearing loss due to an inability to conduct mechanical vibrations through the middle ear is referred to as conductive hearing loss. Some patients have an ossicular chain 37 lacking sufficient resiliency to transmit mechanical vibrations between the tympanic membrane 30 and the oval window 55. As a result, fluidic motion in the cochlea 60 is attenuated. Thus, receptor cells in the cochlea 60 do not receive adequate mechanical stimulation. Damaged elements of ossicular chain 37 may also interrupt transmission of mechanical vibrations between the tympanic membrane 30 and the oval window 55.

Various techniques have been developed to remedy hearing loss resulting from conductive or sensorineural hearing disorder. For example, tympanoplasty is used to surgically reconstruct the tympanic membrane 30 and establish ossicular continuity from the tympanic membrane 30 to the oval window 55. Various passive mechanical prostheses and implantation techniques have been developed in connection with reconstructive surgery of the middle ear 35 for patients with damaged elements of ossicular chain 37. Two basic forms of prosthesis are available: total ossicular replacement prostheses (TORP), which is connected between the tympanic membrane 30 and the oval window 55; and partial ossicular replacement prostheses (PORP), which is positioned between the tympanic membrane 30 and the stapes 50.

- 6 -

Various types of hearing aids have been developed to compensate for hearing disorders. A conventional "air conduction" hearing aid is sometimes used to overcome hearing loss due to sensorineural cochlear damage or mild conductive impediments to the ossicular chain 37.

5 Conventional hearing aids utilize a microphone, which transduces sound into an electrical signal. Amplification circuitry amplifies the electrical signal. A speaker transduces the amplified electrical signal into acoustic energy transmitted to the tympanic membrane 30. However, some of the transmitted acoustic energy is typically detected by the microphone,

10 resulting in a feedback signal which degrades sound quality. Conventional hearing aids also often suffer from a significant amount of signal distortion.

Implantable hearing aid systems have also been developed, utilizing various approaches to compensate for hearing disorders. For example,

15 cochlear implant techniques implement an inner ear hearing aid system. Cochlear implants electrically stimulate auditory nerve fibers within the cochlea 60. A typical cochlear implant system includes an external microphone, an external signal processor, and an external transmitter, as well as an implanted receiver and an implanted single channel or

20 multichannel probe. A single channel probe has one electrode. A multichannel probe has an array of several electrodes. In the more advanced multichannel cochlear implant, a signal processor converts speech signals transduced by the microphone into a series of sequential electrical pulses corresponding to different frequency bands within a

25 speech frequency spectrum. Electrical pulses corresponding to low frequency sounds are delivered to electrodes that are more apical in the cochlea 60. Electrical pulses corresponding to high frequency sounds are delivered to electrodes that are more basal in the cochlea 60. The nerve fibers stimulated by the electrodes of the cochlear implant probe transmit

30 neural impulses to the brain, where these neural impulses are interpreted as sound.

- 7 -

Other inner ear hearing aid systems have been developed to aid patients without an intact tympanic membrane 30, upon which "air conduction" hearing aids depend. For example, temporal bone conduction hearing aid systems produce mechanical vibrations that are coupled to the cochlea 60 via a temporal bone in the skull. In such temporal bone conduction hearing aid systems, a vibrating element can be implemented percutaneously or subcutaneously.

A particularly interesting class of hearing aid systems includes those which are configured for disposition principally within the middle ear 35 space. In middle ear implantable (MEI) hearing aids, an electrical-to-mechanical output transducer couples mechanical vibrations to the ossicular chain 37, which is optionally interrupted to allow coupling of the mechanical vibrations to the ossicular chain 37. Both electromagnetic and piezoelectric output transducers have been used to effect the mechanical vibrations upon the ossicular chain 37.

One example of a partial middle ear implantable (P-MEI) hearing aid system having an electromagnetic output transducer comprises: an external microphone transducing sound into electrical signals; external amplification and modulation circuitry; and an external radio frequency (RF) transmitter for transdermal RF communication of an electrical signal. An implanted receiver detects and rectifies the transmitted signal, driving an implanted coil in constant current mode. A resulting magnetic field from the implanted drive coil vibrates an implanted magnet that is permanently affixed only to the incus 45. Such electromagnetic output transducers have relatively high power consumption requiring larger batteries, which limits their usefulness in total middle ear implantable (T-MEI) hearing aid systems.

A piezoelectric output transducer is also capable of effecting mechanical vibrations to the ossicular chain 37. An example of such a device is disclosed in U.S. Pat. No. 4,729,366, issued to D. W. Schaefer on Mar. 8, 1988. In the '366 patent, a mechanical-to-electrical piezoelectric input transducer is associated with the malleus 40, transducing mechanical

- 8 -

energy into an electrical signal, which is amplified and further processed. A resulting electrical signal is provided to an electrical-to-mechanical piezoelectric output transducer that generates a mechanical vibration coupled to an element of the ossicular chain 37 or to the oval window 55
5 or round window 65. In the '366 patent, the ossicular chain 37 is interrupted by removal of the incus 45. Removal of the incus 45 prevents the mechanical vibrations delivered by the piezoelectric output transducer from mechanically feeding back to the piezoelectric input transducer.

Figure 2 illustrates schematically middle ear regions 35 of different
10 first and second ears of a person, referred to as first and second middle ear regions, of a person implanted with a dual path hearing assistance system 200 according to one embodiment of the present invention. Dual path system 200 may be used instead of a single path system implanted in only one of the first and second middle ear regions. Dual path system 200 may
15 alternatively be used instead of two single path systems that are each implanted in one of the first and second middle ear regions.

In Figure 2, system 200 includes first-ear input transducer 202, which is mechanically coupled to malleus 40 of a first ear, such as the right ear, for receiving mechanical vibrations corresponding to sound. The
20 mechanical vibrations are converted by transducer 202 into an electrical first-ear input signal that is electrically coupled through lead 204 to first-ear input 206 of an electronics unit or device 205.

System 200 also includes second-ear input transducer 208, which is mechanically coupled to malleus 40 of a second ear, such as the left ear, for
25 receiving mechanical vibrations corresponding to sound. The mechanical vibrations are transduced by transducer 208 into an electrical second-ear input signal that is electrically coupled through lead 210 to second-ear input 212 of device 205.

System 200 also includes first-ear output transducer 214, which is
30 electrically coupled through lead 218 to first-ear output 216 of device 205. Transducer 214 is mechanically coupled to cochlea 60 such as through stapes 50 of the first ear for providing mechanical vibrations

corresponding to sound in response to an electrical first-ear output signal received from first-ear output 216 of device 205.

System 200 also includes second-ear output transducer 220, which is electrically coupled through lead 224 to second-ear output 222 of device 205. Transducer 220 is mechanically coupled to cochlea 60 such as through stapes 50 of the second ear for providing mechanical vibrations corresponding to sound in response to an electrical second-ear output signal received from second-ear output 222 of device 205.

System 200 provides, in the embodiment illustrated in Figure 2, dual input signal paths and dual output signal paths. A first-ear input path includes lead 204 from transducer 202 to first-ear input 206 of device 205. A second-ear input path includes lead 210 from transducer 208 to second-ear input 212 of device 205. A first-ear output path includes lead 218 from device 205 to transducer 214. A second-ear output path includes lead 224 from device 205 to transducer 220.

Device 205 includes a signal processor which can process the input signals in different ways to produce the output signals. In one embodiment, the signal from each of the first-ear and second-ear input paths is separately processed in device 205, such as by amplification, filtering, or other signal processing, before being provided at the first-ear and second-ear outputs to the first-ear and second-ear output paths. In another embodiment, signals from the first-ear and second-ear input paths are combined, such as through weighted summing, during processing in device 205, before being provided to the first-ear and second-ear output paths. Variable parameters for the above-described processing in device 205 may be used to optimize signal processing, such as for each of the first and second ears.

Device 205 is implanted in the temporal bone of the skull, or at any other convenient location. For example, device 205 may be implanted in the temporal bone proximate to the first ear and leads 210 and 224 may be subcutaneously disposed along any convenient path between device 205 and the second ear.

- 10 -

Figure 3 illustrates generally another embodiment in which wireless communication is used between device 205 and the second ear, minimizing the need for subcutaneous disposition of leads 210 and 224. In Figure 3, first transmitter/receiver 230 is electrically coupled to device 205.

5 In this patent application, a transmitter/receiver is defined as any apparatus performing either electromagnetic transmission or reception, or both electromagnetic transmission and reception, or any other technique of wireless communication or sensing at a distance such as, for example, ultrasonic, infrasonic, and magnetoresistive techniques. Particular

10 implementations could include amplitude modulation (AM), frequency modulation (FM), frequency-shift keying (FSK), phase-shift keying (PSK), pulse-width modulation (PWM), pulse-code modulation (PCM), or any other suitable communication scheme.

First transmitter/receiver 230 is preferably integrally contained

15 within device 205, but first transmitter/receiver 230 may also be remotely disposed at any other convenient location. Second transmitter/receiver 235 is remotely disposed, either within the second ear, or implanted within the temporal bone proximate to the second ear, or at any other convenient location. Second transmitter/receiver 235 is electrically

20 coupled to at least one, or both, of second input transducer 208 and second output transducer 220. First and second transmitter/receivers 230 and 235 are typically electromagnetically coupled for communication therebetween.

In Figure 3, the second-ear input signal is provided by transducer

25 208 through lead 210B to second transmitter/receiver 235, electromagnetically coupled to first transmitter/receiver 230, and electrically coupled through lead 210A to device 205 for processing. Similarly, device 205 provides at second-ear output 222 the second-ear output signal, which is electrically coupled through lead 224A to first

30 transmitter/receiver 230, electromagnetically coupled to second transmitter/receiver 235, and electrically coupled through lead 224B to transducer 220. A booster amplifier is optionally disposed together with

- 11 -

either one of first transmitter/receiver 230 or second transmitter/receiver 235, or at any other convenient location, to provide amplification of the signals transmitted or received therefrom.

Dual path system 200 is particularly advantageous as an alternative to using a pair of single path systems, each implanted in one of the first and second ears. System 200 requires two procedures for separately implanting the various middle ear hardware in each ear, but it eliminates the need for a separate electronics unit or device associated with each hearing impaired ear. Thus, system 200 avoids implanting two separate electronics units; one electronics unit accommodates both of the first and second ears. Also, the present invention uses a battery disposed within the single electronics unit, device 205. Thus, battery replacement requires explantation of only a single device 205, thereby avoiding explantation of two separate electronics units.

Figure 4 illustrates another embodiment of the invention which is useful for a person having different degrees of hearing loss in each ear. Figure 4 illustrates, by way of example, use of system 200 for profound sensorineural hearing loss in the second ear, but moderate to severe hearing loss in the first ear. In Figure 4, input transducers 202 and 208 are each mechanically coupled to their respective malleus 40 bones and electrically coupled through respective leads 204 and 210 to device 205. The second ear, having profound sensorineural hearing loss, does not benefit from vibration of its stapes. In this example, no output transducer need be associated with the stapes of the second ear. Thus, only first-ear output transducer 214 is used. First-ear output transducer 214 is mechanically coupled to the stapes of the first ear and electrically coupled through lead 218 to first-ear input 216 of device 205.

In Figure 4, transducers 202 and 208 transduce sound vibrations within middle ear portions of respective first and second ears into respective electrical first-ear and second-ear input signals, which are provided through respective first-ear and second-ear input paths to device 205. Device 205 performs signal processing, as described above, including

- 12 -

the combining of signals received along the first-ear and second-ear input signal paths. A resulting electrical first-ear output signal is provided to transducer 214 to vibrate the stapes in the first ear and thereby stimulate the corresponding cochlea. This embodiment advantageously transduces and processes sound vibrations received at each side of the person's head, providing a resulting mechanical stimulation in that ear which does not have profound sensorineural hearing loss. This eliminates the "blind spot" which would occur using a conventional single input path system.

Figure 5 illustrates, by way of example, an additional embodiment of the invention useful for a person having severe conductive hearing loss, such as chronic otitis media or post-tympanomastoidectomy, in the second ear and moderate to severe conductive or sensorineural hearing loss in the first ear. In Figure 5, the invention uses both of the first-ear and second-ear output paths, but only one of the first-ear and second-ear input paths, such as the first-ear input path.

In Figure 5, sound vibrations received by transducer 202 are transduced into an electrical first-ear input signal and electrically coupled via lead 204 to first-ear input 206 of device 205. Device 205 processes the first-ear input signal and provides resulting first-ear and second-ear output signals at first-ear and second-ear outputs 216 and 222 to each of the first-ear and second-ear output paths. The first-ear output signal at first-ear output 216 is electrically coupled through lead 218 to first-ear output transducer 214. The second-ear output signal at second-ear output 222 is electrically coupled through lead 224 to second-ear output transducer 220.

In one embodiment, substantially identical first-ear and second-ear output signals are provided at respective first-ear and second-ear outputs 216 and 222. In another embodiment, device 205 provides first-ear and second-ear output signals of different signal characteristics, with each of the first-ear and second-ear output signals tailored to meet the needs of the particular ear in which its associated output transducer is disposed. Processing parameters of device 205 may also be programmably adjusted to vary the signal characteristics of one or both of the first-ear and second-ear

- 13 -

output signals such that the source or location of origin of the sound may be identified to a degree. Thus, this embodiment provides hearing assistance in both ears though the sound is actually only received from one ear.

5 Figure 6 illustrates an embodiment of the invention which provides a first-ear input path and a second-ear output path. In Figure 6, sound vibrations received by transducer 202 are transduced into an electrical first-ear input signal and electrically coupled via lead 204 to first-ear input 206 of device 205. Device 205 processes the first-ear input signal
10 and provides a resulting second-ear output signal at second-ear output 222 to the second-ear output path. The second-ear output signal at second-ear output 222 is electrically coupled through lead 224 to second-ear output transducer 220, which transduces the second-ear output signal into a mechanical output vibration that is mechanically coupled to stapes 50 of
15 the second ear.

Figures 4-6 also illustrate leaving the incus 45 in place in those ears in which both an input transducer and an output transducer are not disposed, since mechanical feedback is typically not a problem unless both input and output transducers are disposed within the same ear. However,
20 incus 45 may still be optionally removed for other reasons, such as ease of implementations. It is also understood that, when incus 45 is left in place, the corresponding input transducers may be mechanically coupled to the incus 45, rather than malleus 40, so as incorporate the particular frequency characteristics of the incudomalleolar joint between malleus 40 and incus
25 45. When the incus 45 is left in place, the corresponding output transducers may be coupled to the incus 45, and mechanical vibrations coupled to stapes 50 through incus 45. The input and output transducers may also be otherwise mechanically coupled within middle ear 35, including to prosthetic elements implanted therein.

30 Thus, invention provides an at least partially middle ear implantable dual path electronic hearing assist system 200 and method of use in both of a person's ears. The invention includes components for

- 14 -

implantation within the middle ear regions of each ear, and provides: dual input paths; or, dual output paths; or, both dual input paths and dual output paths; or, a single input path corresponding to a first ear and a single output path corresponding to a second ear. The system is capable of
5 use as a partial middle ear implantable (P-MEI) hearing aid system or a total middle ear implantable (T-MEI) hearing aid system.

- 15 -

WHAT IS CLAIMED IS:

1 1. A hearing assist system at least partially implantable in a middle ear,
2 the system comprising:
3 a first-ear input path capable of receiving a first-ear input signal
4 from a first-ear input transducer disposed within a first ear;
5 a first-ear output path capable of transmitting a first-ear output
6 signal to a first-ear output transducer disposed within the first ear;
7 a second-ear input path capable of receiving a second-ear input
8 signal from a second-ear input transducer disposed within a second ear;
9 a second-ear output path capable of transmitting a second-ear output
10 signal to a second-ear output transducer disposed within the second ear;
11 and
12 an electronics unit for receiving and processing at least one of the
13 first-ear and second-ear input signals from at least one of respective first-
14 ear and second-ear input paths, and providing at least one resulting first-
15 ear or second-ear output signal to one of respective first-ear and second-ear
16 output paths.

1 2. A hearing assist system at least partially implantable in a middle ear,
2 the system comprising:
3 a first-ear input transducer, proportioned for disposition within a
4 first ear of a person, for transducing received mechanical sound vibrations
5 within the first ear into an electrical first-ear input signal;
6 a second-ear output transducer, proportioned for disposition within
7 an second ear of the person, for transducing an electrical second-ear output
8 signal into mechanical sound vibrations within the second ear; and
9 an electronics unit electrically coupled to the first-ear input
10 transducer for receiving and processing the first-ear input signal, and
11 electrically coupled to the second-ear output transducer for providing the
12 electrical second-ear output signal.

- 16 -

1 3. The system of claim 2, wherein the first-ear input transducer is
2 mechanically coupled to a malleus bone of the first ear and the second-ear
3 output transducer is mechanically coupled to a stapes bone of the second
4 ear.

1 4. The system of claim 2, further comprising a second-ear input
2 transducer, proportioned for disposition within the second ear of the
3 person, for transducing received mechanical sound vibrations within the
4 second ear into an electrical second-ear input signal, and wherein the
5 electronics unit is electrically coupled to the second-ear input transducer
6 for receiving and processing the second-ear input signal.

1 5. The system of claim 4, wherein the second-ear input transducer is
2 mechanically coupled to a malleus bone of the second ear.

1 6. The system of claim 4, wherein the first-ear output signal is
2 produced from each of the first-ear and second-ear input signals by the
3 electronics unit.

1 7. The system of claim 2, further comprising a first-ear output
2 transducer, proportioned for disposition within the first ear of the person,
3 for transducing an electrical first-ear output signal into mechanical sound
4 vibrations within the first ear, and wherein the electronics unit is
5 electrically coupled for providing the first-ear output signal to the first-ear
6 output transducer.

1 8. The system of claim 7, wherein the first-ear output transducer is
2 mechanically coupled to a stapes bone of the first ear.

1 9. The system of claim 7, wherein the electrical first-ear and second-ear
2 output signals are produced from the first-ear input signal by the
3 electronics unit.

- 17 -

1 10. The system of claim 7, wherein the electrical first-ear and second-ear
2 output signals are produced from the second-ear input signal by the
3 electronics unit.

1 11. A hearing assist system at least partially implantable in a middle ear,
2 the system comprising:

3 a first-ear input transducer disposed within a first ear of a person for
4 transducing received mechanical sound vibrations within the first ear into
5 a corresponding electrical first-ear input signal;

6 a second-ear input transducer disposed within a second ear of the
7 person for transducing received mechanical sound vibrations within the
8 second ear into a corresponding electrical second-ear input signal;

9 a first-ear output transducer disposed within the first ear for
10 transducing an electrical first-ear output signal into mechanical sound
11 vibrations;

12 a second-ear output transducer disposed within the second ear for
13 transducing an electrical second-ear output signal into mechanical sound
14 vibrations; and

15 an electronic device having first-ear and second-ear inputs for
16 receiving respective electrical first-ear and second-ear input signals, and
17 capable of processing the electrical first-ear and second-ear input signals
18 and providing resulting respective first-ear and second-ear output signals
19 at first-ear and second-ear outputs to the first-ear and second-ear output
20 transducers.

1 12. The system of claim 11, wherein communication of each of the
2 second-ear input and output signals between the device and respective
3 second-ear input and output transducers includes wireless
4 communication.

- 18 -

1 13. The system of claim 11, wherein communication of each of the
2 second-ear input and output signals between the device and respective
3 second-ear input and output transducers includes electromagnetic
4 communication.

1 14. The system of claim 11, further comprising:
2 a first transmitter/receiver, electrically coupled to at least one of the
3 second-ear input and second-ear output of the device; and
4 a second transmitter/receiver electrically coupled to at least one of
5 the second-ear input and second-ear output transducers, and
6 electromagnetically coupled to the first transmitter/receiver.

1 15. The system of claim 11, further comprising:
2 a first transmitter/receiver, electrically coupled to each of the
3 second-ear input and second-ear outputs of the device; and
4 a second transmitter/receiver electrically coupled to each of the
5 second-ear input and second-ear output transducers, and
6 electromagnetically coupled to the first transmitter/receiver.

1 16. The system of claim 11, wherein each of the second-ear input and
2 output signals are electrically coupled between the device and respective
3 second-ear input and output transducers through respective second-ear
4 input and output subcutaneous lead wires.

1 17. The system of claim 11, wherein each of the first-ear input and
2 output signals are electrically coupled between the device and respective
3 first-ear input and output transducers through respective first-ear input
4 and output subcutaneous lead wires.

1 18. The system of claim 11, wherein the first-ear and second-ear input
2 transducers are piezoelectric transducers.

- 19 -

1 19. The system of claim 11, wherein said first-ear and second-ear output
2 transducers are piezoelectric transducers.

1 20. A method of assisting hearing within a middle ear, the method
2 comprising:

3 receiving a first-ear input signal provided by a first-ear input
4 transducer disposed within a first middle ear in response to sound
5 vibrations therein;

6 processing the first-ear input signal; and

7 providing a second-ear output signal to a second-ear output
8 transducer disposed within the second middle ear.

1 21. The method of claim 20, further comprising:

2 receiving a second-ear input signal provided by a second-ear input
3 transducer disposed within a second middle ear in response to sound
4 vibrations therein; and

5 processing the second-ear input signal.

1 22. The method of claim 21, further comprising providing a first-ear
2 output signal to a first-ear output transducer disposed within the first
3 middle ear for effecting vibrations therein.

1 23. The method of claim 22, wherein the step of providing the first-ear
2 output signal is in response to the first-ear input signal.

1 24. The method claim 22, wherein the step of providing the second-ear
2 output signal is in response to the second-ear input signal.

1 25. The method of claim 22, wherein at least one of the steps of
2 providing respective first-ear and second-ear output signals is in response
3 to a combination of the first-ear and second-ear input signals.

- 20 -

1 26. The method of claim 22, wherein at least one of the steps of
2 providing respective first-ear and second-ear output signals is in response
3 to a weighted sum of the first-ear and second-ear input signals.

1 27. The method of claim 22, wherein the steps of processing the first-ear
2 and second-ear input signals is carried out in a device that is electrically
3 coupled to each of the first-ear input and output transducers.

1 28. The method of claim 27, wherein at least one of the steps of
2 receiving the second-ear input signal and providing the second-ear output
3 signal includes wireless communication between a first
4 transmitter/receiver that is electrically coupled to the device and a second
5 transmitter/receiver that is electrically coupled to at least one of the
6 second-ear input or output transducers.

1 29. The method of claim 22, wherein the steps of processing the first-ear
2 and second-ear input signals is carried out in a device that is electrically
3 coupled to the first-ear input transducer.

1 30. The method of claim 29, wherein at least one of the steps of
2 receiving the second-ear input signal and providing the second-ear output
3 signal includes wireless communication between a first
4 transmitter/receiver that is electrically coupled to the device and a second
5 transmitter/receiver that is electrically coupled to at least one of the
6 second-ear input or output transducers.

1 31. The method of claim 21, wherein the step of processing the first-ear
2 input signal is carried out in a device that is electrically coupled to the first-
3 ear input transducer.

1 32. The method of claim 31, wherein the step of providing the second-
2 ear output signal includes wirelessly communicating between a first

- 21 -

- 3 transmitter/receiver that is electrically coupled to the device and a second
- 4 transmitter/receiver that is electrically coupled to the second-ear output
- 5 transducer.

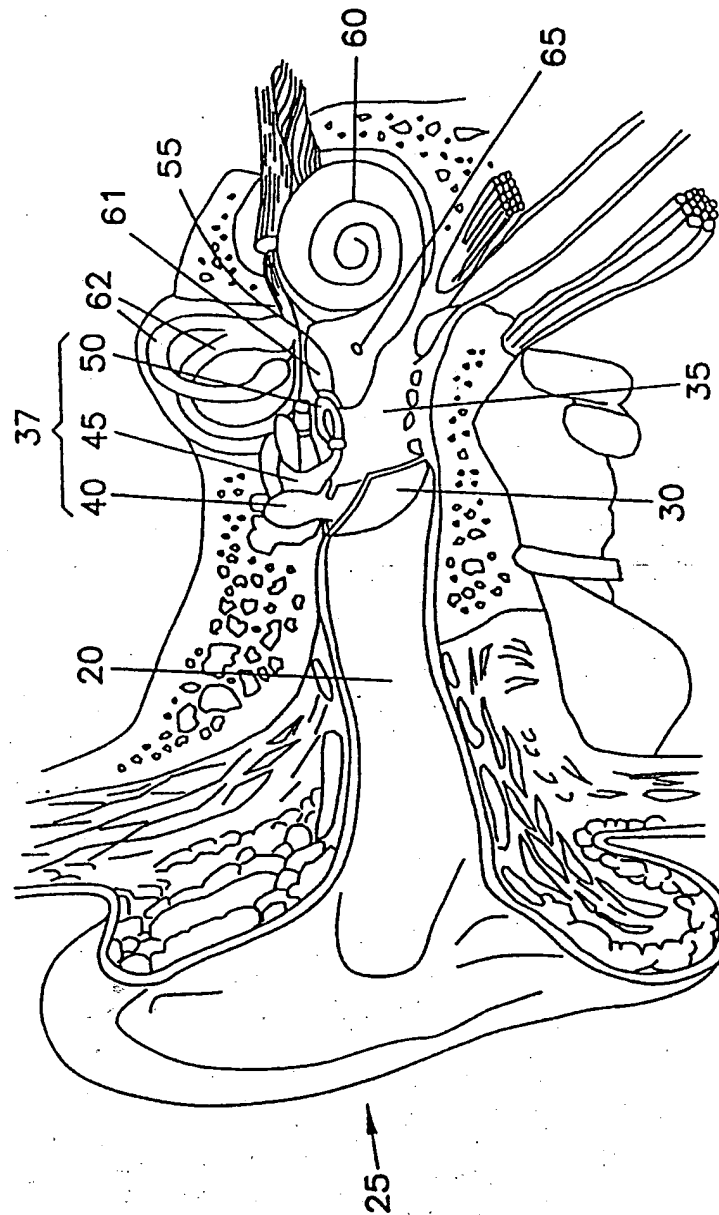


FIG. 1

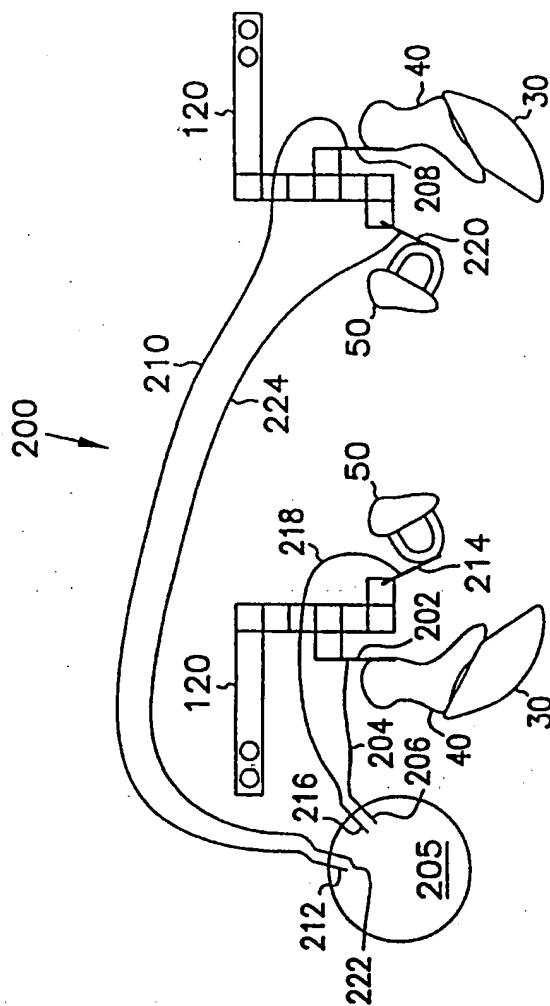


FIG. 2

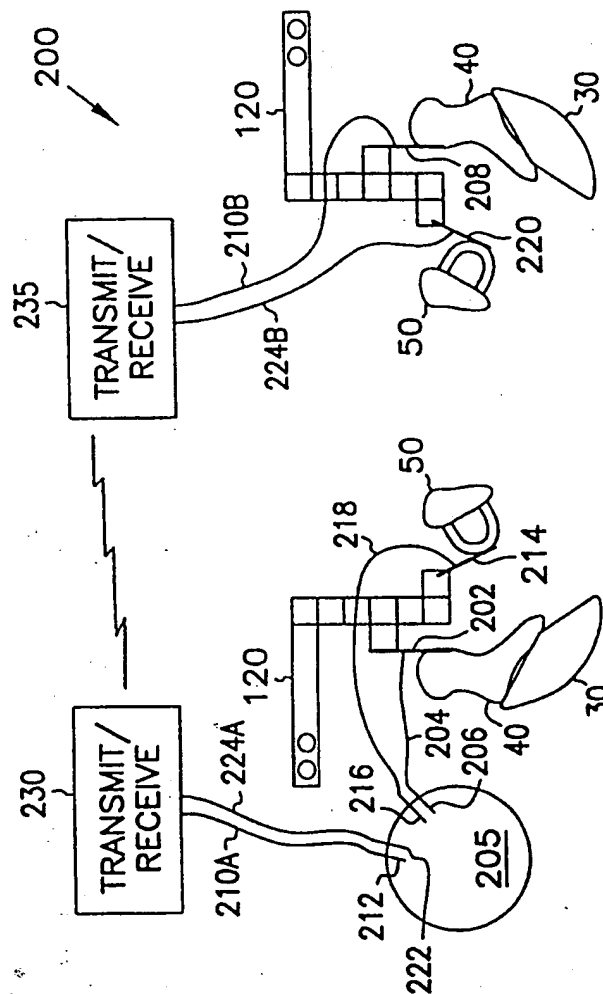


FIG. 3

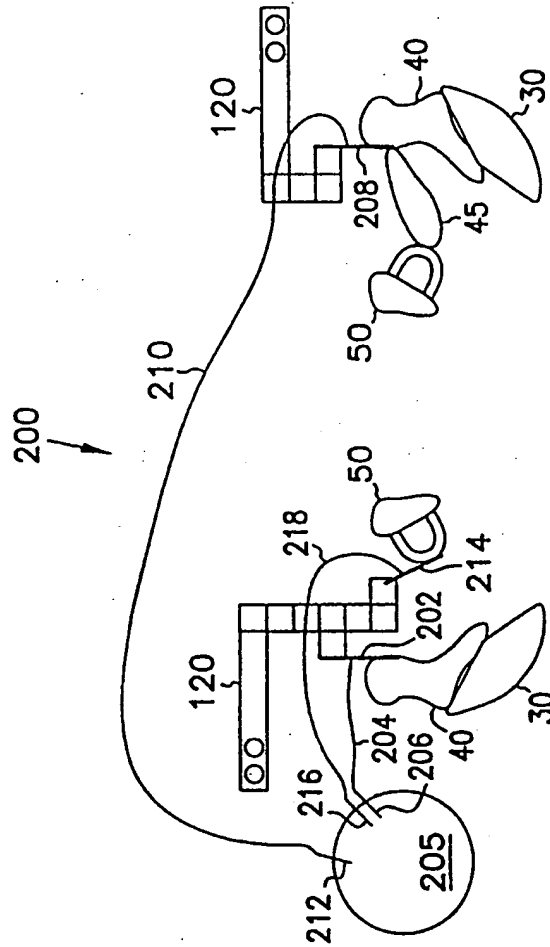


FIG. 4

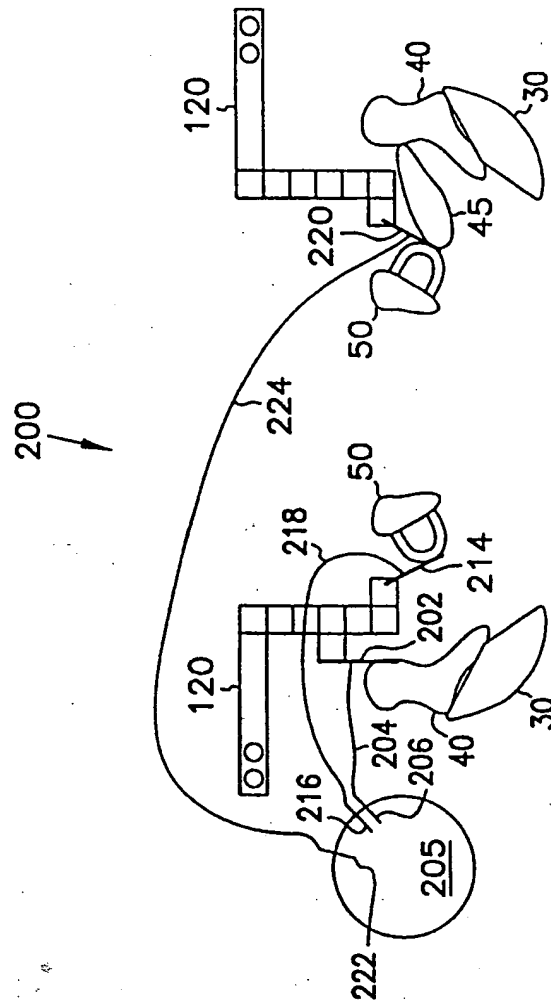
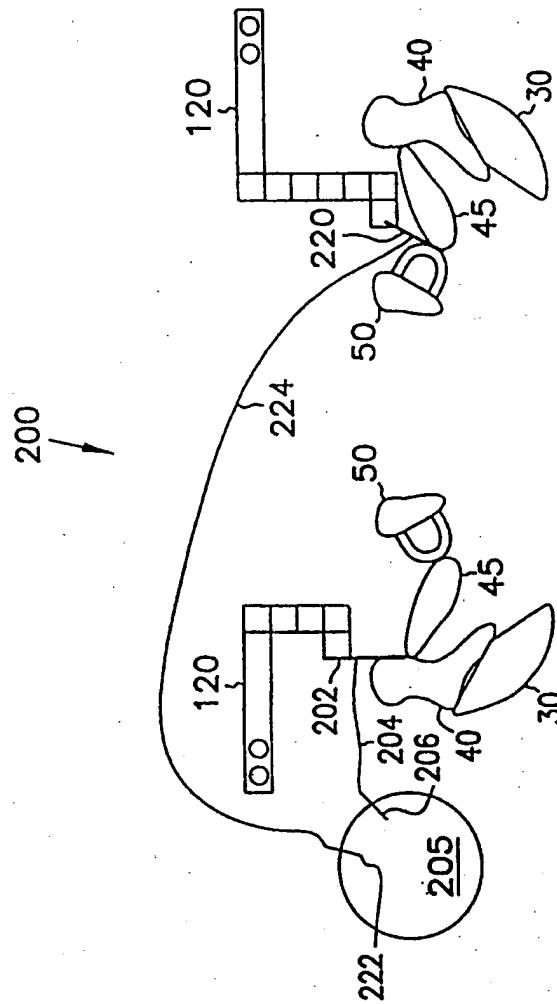


FIG. 5



৬৬৬